

CLAIMS

1. A patch suitable for transdermal or local administration of at least one active principle comprising:

a) a matrix based on pressure sensitive adhesive silicone polymers containing:

5 a-1) said active principle in concentrations between 1 and 10% by weight on the total weight of said dry adhesive matrix,

a-2) said silicone polymers in quantities between 80 and 98% by weight on the total weight of said dry adhesive matrix,

10 a-3) at least one copolymer of cationic type of acrylic and/or methacrylic esters containing amino groups or salified ammonium groups in a concentration between 1 and 10% by weight on the total weight of said adhesive silicone polymers.

b) a support layer on which said adhesive matrix (a) is located,

c) a protective layer disposed on said adhesive matrix.

15 2. The patch as claimed in claim 1, characterised in that the active principle is chosen from the class consisting of drugs with urinary antispastic activity, drugs used for treating prostatic hypertrophy, steroidal hormones, steroidal anti-inflammatories, non-selective and selective beta blockers, calcium antagonists, benzodiazepines.

20 3. The patch as claimed in claim 2, characterised by containing oxybutynin as active principle.

4. The patch as claimed in claim 2, characterised by containing an active principle chosen from terazosin and finasteride.

5. The patch as claimed in claim 2, characterised by containing an active principle chosen from dehydroepiandrosterone and estradiol

25 6. The patch as claimed in claim 2, characterised by containing norethisterone as active principle.

7. The patch as claimed in claim 2, characterised by containing ibuprofen as active principle.

30 8. The patch as claimed in claim 2, characterised by containing piroxicam as active principle.

9. The patch as claimed in claim 2, characterised by containing propranolol as active principle.

10. The patch as claimed in claim 2, characterised by containing at atenolol as active principle.

11. The patch as claimed in claim 2, characterised by containing nifedipine as active principle.

12. The patch as claimed in claim 2, characterised by containing clonazepam as active principle.

13. The patch as claimed in claim 2, characterised by containing triazolam as active principle.

14. The patch as claimed in claim 2, characterised by containing lorazepam as active principle.

15. The patch as claimed in any one of claims 1-14, characterised in that said adhesive silicone polymers are chosen from the group consisting of adhesive silicone polymer (III), adhesive silicone polymer (IV), and relative mixtures of said copolymers (III) and (IV).

16. The patch as claimed in claim 15, characterised in that if containing an active principle containing amino groups, adhesive silicone polymers (III) are used.

17. The patch as claimed in any one of claims 15-16, characterised in that said silicone polymer (III) is at least one polymer chosen from the group consisting of (III-a), (III-b) and (III-c).

18. The patch as claimed in any one of claims 15-16, characterised in that said silicone polymer (IV) is at least one polymer chosen from the group consisting of (IV-a), (IV-b) and (IV-c).

19. The patch as claimed in any one of claims 1-18, characterised in that the copolymer (a-3) is chosen from the group consisting of:

i) copolymers of cationic type based on dialkylaminoalkylmethacrylate, and neutral alkylmethacrylate esters, where alkyl means a C₁-C₁₀ linear or branched alkyl residue, said copolymers having an average molecular weight between 100,000 and 500,000 and in which the ratio of repetitive dialkylaminoalkylmethacrylate/neutral ester units is between 2:1 and 1:2;

ii) copolymers of cationic type based on trialkylammoniumalkylmethacrylate, and neutral alkylmethacrylate esters, neutral alkylacrylate esters, where alkyl means a C₁-C₁₀ linear or branched alkyl residue, said copolymers having an average

molecular weight between 100,000 and 500,000 and in which the alkylmethacrylate and methylmethacrylate/trialkylammoniumalkylmethacrylate ratio is between 40:1 and 20:1;

iii) mixtures of (i) and (ii).

5 20. The patch as claimed in claim 19, characterised in that the copolymer is chosen from the group consisting of:

a-3-1) poly-(butylmethacrylate, (2-dimethylamino)-methacrylate, methylmethacrylate) in which the ratio of said 3 monomers is respectively 1:2:1, and is characterised by an average molecular weight of 150,000;

10 a-3-2) poly(ethylacrylate, methylmethacrylate, trimethylammoniummethylmethacrylate chloride) characterised by an average molecular weight of 150,000 and in which the ratio of said monomers is 1:2:0.2;

a-3-3) poly(ethylacrylate, methylmethacrylate, trimethylammoniummethylmethacrylate chloride) characterised by an average molecular weight of 150,000 and in which the ratio of said monomers is 1:2:0.1; and

a-3-4) mixtures of two or all the copolymers a-3-1), a-3-2), a-3-3).

21. The patch as claimed in claim 20, characterised in that if the active principle is of basic type, said patch contains the component (a-3-3).

20 22. Patch as claimed in claim 20, characterised in that if the active principle is of acid type, said patch contains the component (a-3-2).

23. A process for preparing the patch claimed in any one of claims 1-22, comprising the following stages:

25 α) adding the solution of the cationic polymer of acrylic and/or methacrylic esters containing amino groups or salified ammonium groups (a3) in an organic solvent to the solution of silicone PSA in the same organic solvent used for (a3),

β) adding the active principle to the mixture obtained in the preceding stage (α), and keeping the resultant mixture under stirring for 3 hours,

30 γ) spreading on the support (b) the mixture coming from the preceding stage (β), drying it and applying the protective sheet (c) with conventional machines.

24. The process as claimed in claim 23, characterised by using solutions of silicone polymers in ethyl acetate, in which case the organic solvent of stage (α) is

ethyl acetate.

25. The process as claimed in claim 24, characterised in that said solutions of silicone polymers in ethyl acetate contain said polymer in concentrations of 60% by weight on the total weight of said solution.